Letter Shows Protocol Lapses in Sanofi RSV Infant Vaccine Trial Paused After Participant Death

08/22/2026 // Morgan S. Verity // 1.2K Views

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French pharmaceutical firm Sanofi paused its clinical trial of an experimental respiratory syncytial virus (RSV) vaccine for infants and toddlers after a participating baby died, according to documents obtained through a Freedom of Information (FOI) request and published by Children's Health Defense (CHD) and *ActivistPost*.

The company later shut down the study, with documents showing it did not report safety issues with the vaccine and said it ended the trial because the vaccine was not as effective as hoped. [1][2] A letter obtained by British general practitioner Dr. Peter Selley shows Sanofi told trial sites that it paused the study "to re-educate all participating sites and investigators" on the criteria for determining eligibility for the trial, according to CHD. [3]

Infant Death and Protocol Deviations

The infant's death led to the pause, and the child was later determined to have had a congenital heart defect that should have disqualified the infant from participating, according to CHD. [3] Published guidance identifies babies with cardiac disease as the group at most risk from RSV, with some of these babies dying from the infection. [4] The enrollment of a child with a disqualifying heart condition therefore stands as a notable protocol issue, according to the CHD report. [3]

Regulatory and Company Response

Sanofi's public account of the trial's end did not identify safety problems. According to the documents, the company did not report any safety issues with the vaccine and said it ended the trial because the vaccine was not as effective as hoped. [2]

The U.S. F*ood and Drug Administration* (FDA) has separately accused Sanofi of making misleading claims about Beyfortus, an approved RSV monoclonal antibody. In a letter to the drugmaker, the agency said Sanofi's promotional emails created a "misleading impression" about the approved use of the drug. [5]

Trial Background and Termination

The trial evaluated an experimental RSV vaccine in infants and toddlers, according to the records published with the FOI documents. Sanofi shut the trial down in October 2024 after a child died during the study, according to *ActivistPost*. [2] The company's decision not to report safety issues was reflected in the termination documents, according to CHD. [1]

History of RSV Vaccine Safety Concerns

RSV vaccine development has a record of fatal outcomes in pediatric studies. In the 1960s, an experimental Pfizer RSV vaccine killed two infants, and their families later sued the U.S. government, alleging the children were enrolled without parental knowledge or consent. [6] More recently, Moderna halted its clinical trial of an mRNA RSV vaccine for babies after the shots were linked to severe side effects, according to FDA documents. [7]

The *Centers for Disease Control and Prevention* recommended nirsevimab, marketed as Beyfortus, for infants despite 12 deaths occurring during clinical trials, according to CHD. [8] In those trials, the FDA counted 12 deaths among treated groups versus three among placebo groups, according to researcher Hélène Banoun, Ph.D. [9] Vaccine-safety literature has also warned that antibodies produced by vaccination can worsen later infection, a phenomenon known as antibody-dependent enhancement. [10]

Conclusion: Questions Remain

The internal letter complicates Sanofi's account of why the trial ended. The company said the infant's death was unrelated to the vaccine and that the decision to stop the trial was based on efficacy, but the letter shows the company paused the study to re-educate investigators on eligibility criteria. [1][3]

Infants with cardiac disease are considered particularly vulnerable to severe RSV, making the enrollment of a child with a congenital heart defect a notable lapse. [4] The case adds to a broader record of safety questions around RSV products for infants, including reported deaths in clinical trials and a 1960s pediatric trial that ended in two infant deaths. [8][6]

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Explainer Infographic

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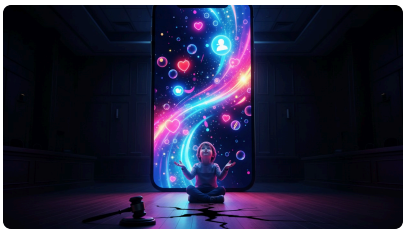

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